

Preliminary Amendment

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Applicant(s): Olav K. LYNGBERG et al.

Serial No.: 09/647,475

Filed: 29 September 2000

Intl. Filing Date: 17 September 1999

For: COMPOSITE DEVICES INCORPORATING BIOLOGICAL MATERIAL AND METHODS

Remarks

The amendments to the specification simply correct typographical and grammatical errors and add no new matter to the specification.

In The Claims

Please amend claim 34 and add new claims 50-99. The new claims are provided below in clean form. Per 37 C.F.R. §1.121, the new claims are also shown in Appendix A with notations to indicate changes made (for convenience, all pending claims, including those added hereby, are provided in Appendix A).

Q9 34. (AMENDED) The device of claim 33 wherein the bacterial cells comprise *E. coli* cells.

Q10 50. (NEW) A microstructure device comprising:
an immobilized cell layer comprising cells capable of providing a detectable response to an analyte material present within a sample; and
a substrate for the immobilized cell layer.

51. (NEW) The microstructure device of claim 50, wherein the immobilized cell layer comprises a microporous polymeric matrix.

52. (NEW) The microstructure device of claim 51, wherein the cells are entrapped within the voids of the microporous polymeric matrix.

53. (NEW) The microstructure of claim 50, wherein the immobilized cell layer comprises cells that have been bio-engineered to produce the detectable response.

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54. (NEW) The microstructure device of claim 50, wherein the detectable response comprises at least one selected from the group consisting of: fluorescence change, change in enzymatic activity, producing a metabolite, pH change, gas evolution, substrate consumption, color change, and mixtures thereof.

55. (NEW) The microstructure device of claim 50, wherein the substrate comprises means capable of detecting the detectable response.

56. (NEW) The microstructure device of claim 55, wherein the substrate further comprises an internal standard for the detectable response.

57. (NEW) The microstructure device of claim 55, wherein the substrate comprises a photosensitive film.

58. (NEW) The microstructure device of claim 55, wherein the substrate comprises a light sensitive electronic chip.

59. (NEW) The microstructure device of claim 50, wherein the substrate is either a substrate that transmits light or a substrate that blocks light.

60. (NEW) The microstructure device of claim 50, further comprising a protective film in contact with at least one of the immobilized cell layer and the substrate.

61. (NEW) The microstructure device of claim 50, further comprising a second polymeric layer.

62. (NEW) The microstructure device of claim 50, wherein the substrate comprises a monofilament that can be pulled through a sample.

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63. (NEW) The microstructure device of claim 50, wherein the substrate comprises multiple filament threads that can be pulled through a sample.

64. (NEW) The microstructure device of claim 50, wherein the immobilized cell layer comprises cells selected from the group consisting of *Escherichia*, *Bacillus*, *Streptomyces*, and combinations thereof.

65. (NEW) The microstructure device of claim 50, wherein the immobilized cell layer comprises at least one polymer selected from the group consisting of an acrylate polymer, a vinyl acetate polymer, a styrene polymer, a butadiene polymer, a carboxylate polymer, and combinations thereof.

66. (NEW) The microstructure device of claim 50, wherein the immobilized cell layer comprises a polymer comprising a (acrylic-co-vinyl acetate) polymer.

67. (NEW) The microstructure device of claim 50, wherein the immobilized cell layer comprises glycerol.

68. (NEW) The microstructure device of claim 50, wherein the immobilized cell layer comprises at least one additive selected from the group consisting of an inorganic material, an amino acid, a pigment, an enzyme, a reactive dye, a photoreactive compound, a bacteriostatic compound, an antibiotic, an antimicrobial agent, an osmoprotectant, a biopolymer, a metal, a chemical catalyst, and mixtures thereof.

69. (NEW) The microstructure device of claim 50, wherein the analyte material comprises an environmental contaminant.

70. (NEW) The microstructure device of claim 50, wherein the sample comprises at least one of seafood tissue, sludge, and soil.

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71. (NEW) A testing structure comprising:
an immobilized cell layer comprising cells engineered to provide a detectable response;
a substrate upon which the immobilized cell layer is provided; and
an interior volume, the microstructure device located within the interior volume, the interior volume configured to accept a sample to determine if the sample contains analyte material that will elicit a detectable response from the immobilized cell layer.
72. (NEW) The testing structure of claim 71, wherein the sample comprises a liquid contained within an absorbent material.
73. (NEW) The testing structure of claim 71, wherein the sample comprises a solid or semi-solid material.
74. (NEW) The testing structure of claim 71, wherein the sample comprises at least one of seafood tissue, sludge, and soil.
75. (NEW) The testing structure of claim 71, wherein the immobilized cell layer comprises a microporous polymeric matrix, wherein the cells are entrapped within voids present within said matrix.
76. (NEW) The testing structure of claim 71, wherein the detectable response comprises at least one selected from the group consisting of: fluorescence change, change in enzymatic activity, producing a metabolite, pH change, gas evolution, substrate consumption, color change, and mixtures thereof.
77. (NEW) The testing structure of claim 71, wherein the substrate comprises means capable of detecting the detectable response.

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78. (NEW) The testing structure of claim 71, further comprising a protective film in contact with at least one of the immobilized cell layer and the substrate.

79. (NEW) The testing structure of claim 71, further comprising a second polymeric layer.

80. (NEW) The testing structure of claim 71, wherein the immobilized cell layer comprises cells selected from the group consisting of *Escherichia*, *Bacillus*, *Streptomyces*, and combinations thereof.

81. (NEW) The testing structure of claim 71, wherein the immobilized cell layer comprises at least one polymer selected from the group consisting of an acrylate polymer, a vinyl acetate polymer, a styrene polymer, a butadiene polymer, a carboxylate polymer, and combinations thereof.

82. (NEW) The testing structure of claim 71, wherein the immobilized cell layer comprises glycerol.

83. (NEW) A test device comprising:
an immobilized cell layer comprising cells bio-engineered to provide a detectable response;
a substrate upon which the immobilized cell layer is provided; and
a housing configured to sufficiently penetrate a solid object, the immobilized cell layer and substrate located within the housing.

84. (NEW) The test device of claim 83, wherein the housing is configured to penetrate a solid object comprising bodily tissue.

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85. (NEW) The test device of claim 83, wherein the housing comprises a syringe, wherein an interior wall of the syringe bears the immobilized cell layer and substrate.

86. (NEW) The test device of claim 83, wherein the immobilized cell layer comprises a microporous polymeric matrix, wherein the cells are entrapped within voids present within said matrix.

87. (NEW) The test device of claim 83, wherein the detectable response comprises at least one selected from the group consisting of: fluorescence change, change in enzymatic activity, producing a metabolite, pH change, gas evolution, substrate consumption, color change, and mixtures thereof.

88. (NEW) The test device of claim 83, wherein the substrate comprises a material capable of detecting the detectable response.

89. (NEW) The test device of claim 83, further comprising a protective film in contact with at least one of the immobilized cell layer and the substrate.

90. (NEW) The test device of claim 83, further comprising a second polymeric layer.

91. (NEW) The test device of claim 83, wherein the immobilized cell layer comprises cells selected from the group consisting of *Escherichia*, *Bacillus*, *Streptomyces*, and combinations thereof.

92. (NEW) The test device of claim 83, wherein the immobilized cell layer comprises at least one polymer selected from the group consisting of an acrylate polymer, a vinyl acetate polymer, a styrene polymer, a butadiene polymer, a carboxylate polymer, and combinations thereof.

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93. (NEW) The test device of claim 83, wherein the immobilized cell layer comprises glycerol.

94. (NEW) A test system comprising:

an immobilized cell layer comprising cells bio-engineered to provide a detectable response and a microporous polymeric matrix, the immobilized cells being entrapped within voids present within the matrix;

a substrate upon which the immobilized cell layer is provided;

a sampling device configured to penetrate a sample and obtain a testing sample;

and

a testing volume containing nutrients and buffers suitable for the immobilized cell layer;

wherein a testing sample is obtained via the sampling device and is placed in the testing volume, the test device configured to determine if the sample contains an analyte material that will elicit a detectable response from the immobilized cell layer.

95. (NEW) The test system of claim 94, wherein the sampling device comprises a hollow coring device configured to remove a test sample, the immobilized cell layer and substrate being provided within the testing volume.

96. (NEW) The test system of claim 94, wherein the immobilized cell layer and substrate are located on the sampling device, the sampling device configured to place the immobilized cell layer in contact with the sample.

97. (NEW) The test system of claim 94, wherein the detectable response comprises at least one selected from the group consisting of: fluorescence change, change in enzymatic activity, producing a metabolite, pH change, gas evolution, substrate consumption, color change, and mixtures thereof.

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98. (NEW) The test system of claim 94, wherein the immobilized cell layer comprises cells selected from the group consisting of *Escherichia*, *Bacillus*, *Streptomyces*, and combinations thereof.

99. (NEW) The test system of claim 94, wherein the immobilized cell layer comprises glycerol and a polymer comprising a (acrylic-co-vinyl acetate) polymer.
